EXHIBIT 1

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URGENT MEDICAL DEVICE CORRECTION

Monday, February 7, 2022

To: Exactech Knee and Ankle Surgeons, Hospitals, Health Care Professionals

Description: Exactech Ultra-High Molecular Weight Polyethylene (UHMWPE) Knee and Ankle Polyethylene Inserts packaged in out-of-specification vacuum bags:

System	Component Description	Marketing Dates	Phase 1 Recall Units (US)	Phase 2 Recall Units (US)	Implanted units in US since 2004
OPTETRAK®	OPTETRAK® All-polyethylene CR Tibial Components	Introduced in the United States in 1994.	211	491	60,926
	OPTETRAK® All-polyethylene PS Tibial Components				
	OPTETRAK® CR Tibial Inserts				
	OPTETRAK® CR Slope Tibial Inserts				
	OPTETRAK® PS Tibial Inserts				
	OPTETRAK® HI-FLEX® PS Tibial Inserts				
OPTETRAK Logic® (referred to as "Logic" below)	OPTETRAK Logic® CR Tibial Inserts	Introduced in the United States in 2009.	2,861	602	60,518
	OPTETRAK Logic® CR Slope Tibial Inserts				
	OPTETRAK Logic® CRC Tibial Inserts				
	OPTETRAK Logic® PS Tibial Inserts				
	OPTETRAK Logic® PSC Tibial Inserts				
	OPTETRAK Logic® CC Tibial Inserts				
TRULIANT®	TRULIANT® CR Tibial Inserts	Introduced in the United States in 2017.	5,144	53,207	24,727
	TRULIANT® CR Slope Tibial Inserts				
	TRULIANT® CRC Tibial Inserts				
	TRULIANT® PS Tibial Inserts				
	TRULIANT® PSC Tibial Inserts				
VANTAGE®	VANTAGE® Fixed-Bearing Liner Component	Introduced in the United States in 2016.	518	3,461	1,561

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Dear Exactech Surgeon,

The purpose of this letter is to provide an important update on the status of our knee and ankle arthroplasty polyethylene inserts and the recall we initiated on August 31, 2021 and important recommendations for surgeons.

After extensive testing, we have confirmed that most of our inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "non-conforming") vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

Exactech is now expanding the recall to include all knee and ankle arthroplasty polyethylene inserts packaged in non-conforming bags **regardless of label or shelf life**. During the period between August 2021 and January 2022, non-conforming knee and ankle devices have been shipped and implanted by surgeons. In later sections of this letter, we will describe how surgeons can access lists of all their patients who have been implanted with non-conforming devices. FDA has classified this field action as a class II recall, meaning that exposure to the product may cause temporary or medically reversable health consequences or where the probability of serious health consequences is remote.

The design of these systems has evolved over time, but the UHMWPE materials have been consistent. More specifically, all three of these generations of Exactech knee systems have had polyethylene inserts packaged in non-conforming bags at various points during their respective market tenures. The original Optetrak Knee system, introduced in 1992, has shown statistically significant higher overall revision rates as compared to other TKA's in the Australian, United Kingdom and New Zealand registries. The data cited below do not include data on the Logic or Truliant knee systems.

The Australian Registry reported a total of 374 TKR revision procedures among 3,684 primary Optetrak TKRs with up to 14- to 20-years follow-up for each prosthesis combination. Every Exactech Optetrak TKR polyethylene component combination demonstrated statistically significant increased revision rates compared to other TKR systems (N=668,852) with at least one and a half years of follow-up with hazard ratios ranging from 1.84 to 5.85 ($p<0.001$)[1,4-7]. The United Kingdom Registry reported that the Exactech Optetrak TKR System utilizing the cruciate retaining femoral component (N=1,638) had statistically significant increased cumulative revision rates compared to all TKRs (N=1,145,052) at the 3, 5, 10, 13 and 15-year timepoints.[2] The New Zealand Registry reported a total of 63 TKR revision procedures among 661 primary Optetrak TKRs. The Optetrak TKR revision rate was 1.015/100 component years compared to all other primary TKRs (N=118,430) which had a revision rate of 0.48/100 component years and represented a statistically significant value greater than a two-fold increased revision rate.[3]

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Additionally, the reasons for revision potentially associated with polyethylene wear (e.g., loosening, lysis, pain) were increased three- to seven-fold in the most used Exactech Optetrak TKR combination (Optetrak-PS/Optetrak) which had a total of 263 TKR revision procedures among 2,410 primary TKRs when compared to other TKRs in the Australian Registry[4]. The reasons for these increased revision diagnoses related to accelerated polyethylene wear may be related to the non-conforming packaging.

We are uncertain if the root cause of these Optetrak higher and earlier than expected revision rates are due only to the non-conforming vacuum bags. The uncertainty in assessing the root cause stems from the fact that the registry data of the Optetrak Knee System report outcomes for polyethylene components in both conforming and non-conforming packaging, and the registries do not contain packaging information.

Exactech ankle arthroplasty systems have been represented by one implant system, marketed since 2017, and known as the Vantage® Total Ankle system. As described above, polyethylene inserts for the Vantage system have been packaged in non-conforming bags.

Please be advised that beginning in August 2021, Exactech recalled product with a labeled 8-year shelf-life that would have a shelf life of 5 years or greater as of August 31, 2022. Exactech is expanding the recall to include the remaining 55,269 non-conforming Exactech Knee and Ankle Ultra-High Molecular Weight Polyethylene (UHMWPE) inserts in the field, regardless of shelf life. There are approximately a total of 147,732 inserts implanted in the US since 2004 that were produced with non-conforming packaging.

Exactech is advising surgeons to avoid implanting nonconforming devices. A list of product codes, product description and serial numbers can be found at: https://www.exac.com/recall. Your agent will work with you to remove non-conforming devices from inventory. Additionally, we are requesting all conforming and non-conforming devices be returned to Exactech. We will sort and work to provide you with complete sets of conforming inserts as quickly as possible.

For all patients historically implanted with polyethylene devices in non-conforming bags, surgeons should maintain an appropriate index of suspicion for patients with any new or worsening pain, inability to bear weight, grinding or other noise, swelling, or instability in their knee or ankle . Note that registry data suggests that the reasons for revision related to accelerated UHMWPE wear in the most used prosthesis combination (Optetrak-PS/Optetrak) were increased 3- to 7-fold compared to all other TKR systems.[4] The reasons for these increased revision diagnoses related to accelerated polyethylene wear may be related to the non-conforming packaging.

In addition, Exactech recommends that surgeons closely monitor the affected knee and ankle patients for potential wear, osteolysis, and associated failure modes, regardless of polyethylene shelf-life and regardless of the time period that has elapsed since index arthroplasty. If a failed device is suspected, consider performing X-rays to further evaluate the device. Pre-emptive removal of non-painful, well-functioning Exactech knee and ankle devices from asymptomatic patients is not recommended. Decisions about removing or exchanging the device should be made by health care providers in consultation with the patient or caregiver on a case-by-case basis. As part of shared decision-making, discuss the benefits and risks of all relevant treatment options for painful arthritic knee and ankle joints with your patients.

For patients who exhibit premature polyethylene wear, the surgeon should consider revision surgery per their clinical judgment. If the surgeon desires to perform an isolated polyethylene exchange, Exactech can provide new polyethylene knee or ankle inserts that are packaged in conforming vacuum bags that contain the specified secondary EVOH oxygen barrier layer.

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Exactech is providing surgeons with a draft letter to their patients who have been implanted with Exactech knee and ankle devices packaged in non-conforming bags. We recommend surgeons customize the letter and send it to patients implanted with non-conforming devices. Additionally, Exactech is prepared to provide you (1) a list of all your knee and ankle arthroplasty patients who received devices in non-conforming bags, to assist in clinical follow-up efforts, (2) a frequently asked questions page online to assist you, and (3) a tool on Exactech's website that will empower a patient to enter her/his implant serial number and confirm whether or not that implanted device is non-conforming. Knee and ankle patient communication letters should be sent to and discussed with patients as appropriate. We will contact you separately about your willingness to participate in a voluntary program to provide Exactech with statistics on patient follow-up per a new FDA Patient Science and Engagement Program.

Finally, Exactech has implemented third-party administrator (TPA) services to assist patients with out-of-pocket costs and claims management related to this recall. Information regarding these services can be found on the Exactech website at: https://www.exac.com/recall.

If it is helpful, we would appreciate the opportunity to set up a conference call/WebEx with you and our corporate leadership team to discuss the issues around this recall, the TPA services, provision of patient lists and management, drafted letters to patients, or any other questions in greater detail. Please correspond with the email address, *packaging-bags@exac.com*, or call us at 1.888.892.5635 if you wish to meet and we will arrange a time as soon as possible.

In conclusion, we would like to reiterate our sincere thanks for your support of Exactech over the years and for taking the time to read this note. We look forward to hearing from you.

Sincerely,

Darin Johnson (Feb 7, 2022 18:24 EST)

Sharat Kusuma (Feb 7, 2022 18:24 EST)

Darin Johnson, President and Chief Executive Officer
Sharat Kusuma, MD, FAAOS, Senior Vice President, and Chief Medical Officer

References

1. Australian Orthopaedic Association National Joint Replacement Registry: Hip, Knee & Shoulder. Annual Report 2021. Adelaide, Australia: AOA, 2021.
2. United Kingdom National Joint Registry: 18th Annual Report. Annual Report 2020. United Kingdom: United Kingdom National Joint Registry, 2021.
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4. Australian Orthopaedic Association National Joint Replacement Registry: Optetrak-PS/Optetrak Total Knee Investigation 2021. Adelaide, Australia: AOA, 2021.
5. Australian Orthopaedic Association National Joint Replacement Registry: Optetrak-CR (cemented)/Optetrak-CR (cemented) Total Knee Investigation 2021. Adelaide, Australia: AOA, 2021.
6. Australian Orthopaedic Association National Joint Replacement Registry: Optetrak-PS/Optetrak-PS Total Knee Investigation 2021. Adelaide, Australia: AOA, 2021.
7. Australian Orthopaedic Association National Joint Replacement Registry: Optetrak-PS/Optetrak RBK Total Knee Investigation 2021. Adelaide, Australia: AOA, 2021.